

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG, ABBOTT)	
BIORESEARCH CENTER, INC., ABBOTT)	C.A. No. 4:09-CV-11340 (FDS)
BIOTECHNOLOGY, LTD.)	
)	
Plaintiffs,)	JURY TRIAL DEMANDED
)	
v.)	
)	
CENTOCOR ORTHO BIOTECH, INC.,)	
CENTOCOR BIOLOGICS, LLC.)	
)	
Defendant.)	
)	

**PLAINTIFFS' SUPPLEMENTAL BRIEF IN RESPONSE TO THE COURT'S
JANUARY 30, 2012 ORDER**

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I. INTRODUCTION

Abbott submits this supplemental brief pursuant to the Court's Order of January 30, 2012 (D.I. 328), to address the relevance of the decisions in *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, 659 F.3d 1186 (Fed. Cir. 2011) ("*Streck I*") and *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, 665 F.3d 1269 (Fed. Cir. 2012) ("*Streck II*") in this action and in the related action under 35 U.S.C. § 146. Specifically, the Court sought the parties' views as to the effect of those decisions on two issues:

(1) Whether consideration of validity in an infringement action may be precluded by either (a) a prior BPAI interference decision that is subject to judicial review or (b) a contemporaneous decision of a district court in a co-pending Section 146 action; and

(2) Whether, in a trial for concurrent infringement and Section 146 actions, resolution of validity issues by the court is consistent with *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500 (1959).

Abbott submits that while the *Streck* opinions clarify the Federal Circuit's case law concerning the nature of proceedings under Section 146,¹ they do not provide significant guidance on the two questions posed by the Court because of the different procedural context presented in those cases, where the infringement action was tried and judgment entered before the Section 146 action was filed. Thus, Abbott is not aware of any precedent that directly answers the Court's questions. However, existing case law in analogous contexts supports the conclusion that Seventh Amendment concerns are irrelevant to the issues presented by the parties' summary judgment motions or to the manner in which future proceedings should be conducted in these two actions.

¹ Additional guidance on the rules applicable to a Section 146 proceeding may be forthcoming from the Supreme Court, when its decision in *Kappos v. Hyatt*, No. 10-1219, is issued. *Kappos v. Hyatt*, 131 S. Ct. 3064 (2011) (certiorari granted on standards applicable to proceedings under Section 145).

In particular, with respect to Question 1(a), it is Abbott's position that, under existing law, an interference proceeding offers a litigant a full and fair opportunity to litigate patent validity before the Board of Patent Appeals and Interferences ("BPAI" or "Board"), and the decision of the BPAI is therefore final and binding for the purpose of collateral estoppel, regardless of whether it is still subject to further judicial review under Section 146 in the district court or the Federal Circuit. Therefore, the BPAI decision can and should preclude consideration of validity in the instant infringement action. The same analysis is applicable to the question posed in 1(b): a decision of a district court in a Section 146 proceeding would also result in collateral estoppel. These conclusions follow from the principle that the pendency of an appeal does not, in general, diminish the res judicata effect of a decision by a lower tribunal. The only difference between the status of the Board's decision before review by the district court and the district court's Section 146 decision is that Centocor concedes collateral estoppel bars relitigation of at least certain invalidity defenses after the district court's decision. (Summ. J. Hr'g Tr. 6:3-6, Dec. 7, 2011.)

With respect to Question 2, because the BPAI's decision is a final agency decision entitled to preclusive effect in the infringement action, the Supreme Court's decision in *Parklane Hosiery Co. v. Shore*, 439 U.S. 322 (1979), is directly on point and establishes that the Seventh Amendment is not an issue. Moreover, even if the BPAI decision was viewed as not having preclusive effect in the infringement action, the Seventh Amendment does not pose a bar to the Court resolving the Section 146 action prior to or concurrently with a jury trial in the infringement action. The holding in *Beacon Theatres* is not applicable to the circumstances presented here because the infringement action and the Section 146 appeal are two different actions, the latter of which arises from a separate statutory scheme. Further, there can be no

violation of the Seventh Amendment for the additional reason that Centocor waived its right to a jury trial on validity issues in electing to challenge validity via the interference and subsequent commencement of the action under Section 146.

II. ARGUMENT

A. The Relevance and Effect of the *Streck* Decisions

The Federal Circuit's decisions in *Streck I* and *Streck II* elucidate the nature of proceedings under Section 146. However, they do not directly answer the two questions posed by the Court, nor do they directly address the collateral estoppel issue presented in Abbott's Motion for Summary Judgment No. 2.

The *Streck* decisions resolved the appeals of a jury-tried infringement action and a subsequent bench-tried Section 146 action, both involving identical parties and patents. The Section 146 action was not initiated until after trial and entry of judgment in the infringement action. *Streck II*, 665 F.3d at 1279. The appeals from both the Section 146 action and the infringement action were briefed and argued contemporaneously. *Streck I* resolved the appeal of the district court's decision with respect to the Section 146 proceeding; *Streck II* resolved the appeal with respect to the infringement action.

In *Streck I*, the Federal Circuit affirmed the district court's reversal of a Board decision finding that the accused infringer was the first inventor. The record before the district court, and on appeal, included the record in the previously tried infringement action together with the record in the interference proceeding. The pertinent issue in *Streck I* concerned the use of this record in the Section 146 action. While this issue is not relevant to what issues should be collaterally estopped in a later infringement action, it is relevant to the proper standard of review in a Section 146 proceeding. Without addressing whether a party may raise new issues or

arguments in a Section 146 proceeding, the *Streck I* court held that in that case, “the district court appropriately considered additional evidence and conducted a *de novo* determination of the issue of priority under § 146” based on that additional evidence. *Streck I*, 659 F.3d at 1191.

In *Streck II*, which resolved the appeal in the infringement action, the relevant issue was whether the district court erred in denying accused infringer R & D’s motion for renewed JMOL and motion for a new trial on the issue of priority of invention, after the jury found in favor of patent holder Streck on that issue. *Streck II*, 665 F.3d at 1292. The *Streck II* court answered in the negative and affirmed the district court’s decision. *Id.* In doing so, it relied on its *Streck I* affirmance of the district court’s award of priority to Streck in the Section 146 action, reasoning that resolution of priority in the *Streck I* appeal of the Section 146 action, where R & D’s burden had been lower, controlled the priority issues in the *Streck II* appeal of the infringement action, where R & D’s burden was higher:

Specifically, in the § 146 action, R & D had to establish priority by a preponderance of the evidence whereas in this appeal, R & D had to show its priority defense by clear and convincing evidence. As such, our decision in [*Streck I*] that R&D failed to establish priority by a preponderance of the evidence necessarily means that R&D could not meet the clear and convincing burden required in this case.

Id.

Streck II demonstrates that, if Centocor were unable to prove priority and invalidity in the interference proceeding under a lower, preponderance standard of proof, it should not be permitted to relitigate the identical validity issue in the infringement action under the higher clear and convincing standard of proof. However, because of the order of proceedings and the congruence of the district court’s decision in the Section 146 proceeding and the jury’s verdict, the cases do not directly answer the Court’s questions.

B. Response to Question No. 1: Consideration of Validity in An Infringement Action May Be Precluded by a BPAI Interference Decision or a Section 146 Decision

Abbott submits that consideration of the validity issues in an infringement action may be precluded by either (a) a prior BPAI interference decision that is subject to further judicial review under either 35 U.S.C. §§ 141 or 146; or (b) a decision of a district court in a co-pending Section 146 action that is subject to further judicial review via appeal to the Federal Circuit.

The consideration of validity in an infringement action is appropriately precluded by a prior interference decision as long as (1) the interference action involved the issue of validity, (2) the issue of validity was actually litigated, (3) the issue of validity was determined by a valid and binding final judgment; and (4) the determination of validity was essential to the judgment. *Ramallo Bros. Printing, Inc. v. El Dia, Inc.*, 490 F.3d 86, 90 (1st Cir. 2007). Decisions of administrative agencies acting in a judicial capacity are given collateral estoppel effect as long as the parties had a full and fair opportunity to litigate. *U.S. v. Utah Constr. & Mining Co.*, 384 U.S. 394, 421-22 (1966); *Aunyx Corp. v. Canon U.S.A., Inc.*, 978 F.2d 3, 7 (1st Cir. 1992). For the reasons already set forth in Abbott's opening and reply briefs in support of Abbott's Motion for Summary Judgment No. 2, Centocor had that opportunity. (Abbott's Mem. No. 2 at 10 (D.I. 238); Abbott's Reply No. 2 at 5-6 (D.I. 284).)

The fact that the BPAI decision is subject to further judicial review is immaterial because it does not affect the finality of the decision for the purpose of collateral estoppel. The question of finality for this purpose is not one of "technical" finality focusing on whether the decision is appealable. Rather, it is a question of whether the decision is sufficiently final to accord it res judicata effect – whether "the litigation of a particular issue has reached such a stage that a court sees no really good reason for permitting it to be litigated again." *O'Reilly v. Malon*, 747 F.2d

820, 823 (1st Cir. 1984). This analysis looks at “the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review.” *Id.* As with the judgment of a district court, the fact that the BPAI’s decision might be reversed on appeal, either by this Court or the Federal Circuit is irrelevant to its finality for the purpose of collateral estoppel. (Abbott’s Reply No. 2 at 7-8 (D.I. 284).) *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999) (“[T]he pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding”) (citing *Deposit Bank v. Bd. of Councilmen of City of Frankfort*, 191 U.S. 499 (1903)). And, as Abbott noted at oral argument on its Motion for Summary Judgment No. 2, that the BPAI’s interference decision is “final” for purposes of collateral estoppel is perhaps best demonstrated by the fact that, under 35 U.S.C. § 141, Centocor had the option to appeal the BPAI decision directly to the Federal Circuit. (Summ. J. Hr’g Tr. 17:11-19, Nov. 22, 2011.)

The same collateral estoppel analysis applies with respect to the preclusive effect of a district court’s determination of validity issues in a Section 146 action in a co-pending infringement action, with the additional consideration that Centocor concedes a district court decision on the issue of patent validity in the Section 146 action bars relitigation of those same invalidity defenses in the separate infringement action. (Summ. J. Hr’g Tr. 6:3-6, Dec. 7, 2011 (“[I]f there’s a final decision in the 146 action, that would bar presenting an obviousness defense in the infringement action[.]”).) Therefore, if the Court were to decide the issue of validity in the Section 146 action before that issue was addressed in the infringement action, the Court’s decision would have preclusive effect in the infringement action. *See, e.g., Parklane*, 439 U.S. 322 (permitting the offensive use of collateral estoppel to prevent relitigation before a jury of factual issues determined in bench trial of separate proceeding); *Pall Corp. v. Fisher Scientific*

Co., 962 F. Supp. 210, 213 (D. Mass. 1997) (holding that issue of validity is precluded by district court's prior determination of validity, "[e]ven assuming that [defendant] now seeks to invalidate the patent on different grounds than those asserted" in the prior action); *see also Streck II*, 665 F.3d at 1292 (failure of party to establish priority of invention by a preponderance of the evidence in Section 146 action necessitates conclusion that party could not meet higher clear and convincing burden required in infringement action).

C. Response to Question No. 2: Resolution of Validity Issues by the Court is Consistent with *Beacon Theatres*

With respect to the Court's second question, Abbott submits that the Seventh Amendment analysis of *Beacon Theatres*, 359 U.S. 500, is irrelevant to these actions.

In analyzing the Seventh Amendment issue, two possible scenarios should be considered. The first scenario assumes that the Court determines that the BPAI interference decision is sufficiently final such that it should be given preclusive effect in the infringement action. Under this scenario, the Supreme Court's holding in *Parklane*, 439 U.S. 322, makes clear that there is no Seventh Amendment issue.

Parklane involved a stockholder's class action against Parklane and other corporate defendants who allegedly issued a materially false and misleading proxy statement. 439 U.S. at 324. Before that action was tried, the SEC sued the same defendants, alleging that the proxy statement was materially false and misleading in essentially the same respects. *Id.* Following a bench trial, judgment was entered for the SEC. *Id.* at 324-25. The Supreme Court held that 1) the defendants were collaterally estopped from relitigating in the jury trial the question of whether the proxy statement was materially false and misleading and 2) plaintiff's use of offensive collateral estoppel to preclude relitigation of issues in the legal action, based on a non-jury decision in the equitable action brought by the SEC, would not violate the defendants'

Seventh Amendment right to a jury trial. *Id.* at 332-37. *See also Ritter v. Mount St. Mary's College*, 814 F.2d 986, 991 (4th Cir. 1987) (“Parklane decided that the judicial interest in the economical resolution of cases, which interest underlies the doctrine of collateral estoppel, does override the interest of the plaintiff in re-trying before a jury the facts of a case determined by a court sitting in equity.”). As in *Parklane*, the BPAI’s non-jury determination can have collateral estoppel effect in a separate infringement action, without violating the Seventh Amendment.

The second scenario assumes that the Court determines that the BPAI decision is not sufficiently final to be given preclusive effect in the infringement action. Under this scenario, the question becomes whether the Court must order the proceedings so that the jury determines the validity issue in the infringement action before the Court considers that issue in the Section 146 action. Supreme Court precedent subsequent to *Beacon Theatres* indicates that the Seventh Amendment does not prevent this Court from deciding the issue of validity in the Section 146 action prior to a jury trial in the infringement action. These subsequent cases establish that the holding in *Beacon Theatres* is primarily applicable to situations in which legal and equitable claims are joined in a *single* action. *Beacon Theatres* is inapplicable here, where there are two separate actions, one of which is an appeal from an administrative agency, that happen to be co-pending.

In *Parklane*, the Supreme Court clarified *Beacon Theatres*, explaining that it is “no more than a general prudential rule” that “when legal and equitable claims are *joined in the same action*, the trial judge has only limited discretion in determining the sequence of trial and ‘that discretion . . . must, wherever possible, be exercised to preserve jury trial.’” *Parklane*, 439 U.S. at 334 (emphasis added) (omission in original) (quoting *Beacon Theatres*, 359 U.S. at 510) (finding no violation of Seventh Amendment where equitable determination of factual issues in

one action was given collateral estoppel effect in separate legal action). And in *Katchen v. Landy*, 382 U.S. 323, 339-40 (1966), the Court noted that *Beacon Theatres* “recognize[s] that there might be situations in which the Court could proceed to resolve the equitable claim first even though the results might be dispositive of the issues involved in the legal claim.”

Indeed, we have located no case decided since *Parklane* in which the Seventh Amendment was found to be implicated outside the context of a single action. That is, no court has held that in the situation of two separate actions involving common issues of fact, a court must order proceedings so that the jury action is tried before the non-jury action. Further, at least one Court of Appeals decision has found the rule in *Beacon Theatres* to be inapplicable even when two actions have been consolidated under Rule 42(a):

The *Beacon Theatres* analysis applies when the legal and equitable claims are joined either in the same complaint, *Owens-Illinois, Inc. v. Lake Shore Land Co.*, 610 F.2d 1185, 1190 (3d Cir. 1979), or in the same action through a complaint and counterclaim. *Torcomian*, 722 F.2d at 1104. Here, however, we are presented with consolidation of legal and equitable claims under Rule 42(a). Reevaluating equity’s jurisdiction over legal issues in light of “the liberal joinder provisions of the Federal Rules which allow legal and equitable causes to be brought and resolved in one civil action,” the Supreme Court in *Beacon Theatres* referred specifically to Rules 1, 2, and 18 in a footnote. 359 U.S. at 509 n. 14, 79 S. Ct. at 956 n. 14. Conspicuous by its absence from this list was Rule 42 (“Consolidation; Separate Trials”).

Newfound Mgmt. Corp. v. Lewis, 131 F.3d 108, 116 (3d Cir. 1997) (in consolidated cases of quiet title and trespass, upholding district court’s determination of property lines before submission of other issues to a jury, because consolidation “[did] not merge the suits into a single cause, or change the rights of the parties”) (internal quotations omitted).

Here, not only is the Section 146 action a separate proceeding from the infringement action,² but, as a species of appeal, it is fundamentally different from the infringement action. Section 146 permits any party to an interference dissatisfied with the decision of the BPAI on the interference to have a remedy via a civil action in the district court. As an appeal, the scope of the action is framed by the issues and record before the Board. Further, the primary concern of an interference is priority of invention and a determination of who among multiple inventors is entitled to a patent on the same or similar subject matter. MPEP § 2301 (“An interference is declared to assist the Director of the United States Patent and Trademark Office in determining priority, that is, which party first invented the commonly claimed invention within the meaning of 35 U.S.C. 102(g)(1).”). Unlike an infringement action, a Section 146 action is thus an integral part of the statutory framework for issuing patents.

As illustrated by the Supreme Court’s *Katchen* decision, nothing in the Seventh Amendment requires the Court to disregard this statutory framework in favor an infringement action. In *Katchen*, the Supreme Court rejected a creditor’s argument that allowing the bankruptcy court to summarily determine the bankruptcy trustee’s preference claims against him wrongfully deprived him of his Seventh Amendment right to a jury trial. 382 U.S. at 325. The creditor in *Katchen* argued, among other things, that because the preference issues could have been presented as legal issues in a suit by the trustee rather than as equitable issues in the bankruptcy proceeding, the bankruptcy court should have stayed its proceedings and directed the trustee to commence a civil action so as to preserve the creditor’s right to a jury trial. *Id.* at 338. The Court observed that the creditor’s argument would force the bankruptcy court to suspend its proceedings and initiate a plenary suit every time a jury trial was demanded on a preference

² The cases were consolidated only for purposes of discovery. (D.I. Feb. 25, 2010, Electronic Clerk’s Notes of Scheduling Conference (“Court orders case 10CV40003 consolidated into this case [09CV11340] for fact discovery purposes”).)

claim. *Id.* at 339. The Court reasoned that such a result would undermine the statutory bankruptcy scheme, a concern that had not been an issue in *Beacon Theatres*: “In neither *Beacon Theatres* nor *Dairy Queen* was there involved a specific statutory scheme contemplating the prompt trial of a disputed claim without the intervention of a jury.” *Id.* The Court concluded that to implement congressional intent and effectuate the equitable purposes of bankruptcy adjudication, the bankruptcy court could summarily adjudicate equitable claims presented to it, even if their determination would be dispositive of what would otherwise be legal claim issues. *Id.* at 339-40.

To assert that a district court cannot resolve validity issues as part of a statutorily-devised Section 146 proceeding until those validity issues are first resolved in a separate infringement jury trial would similarly undermine the statutory patent scheme designed “to secure the just, speedy, and inexpensive determination of the proceeding.” 37 C.F.R. § 41.125. Such a result would be particularly inappropriate here, where Centocor made the strategic decision to provoke the interference in the Patent Office where it could challenge validity based on the lower standard of proof. Having made that strategic decision and having lost, it would be perverse if the prudential rule of *Beacon Theatres* was interpreted to require the Court to order the trials so as to give Centocor two additional bites at the apple, the first in the infringement case under the higher standard of proof, and the second (even if Centocor lost on the issue of validity in the infringement case) in the Section 146 action under the lower standard of proof. It is precisely this type of incongruous circumstance that permits the Court “to resolve the equitable claim first even though the results might be dispositive of the issues involved in the legal claim.” *Katchen*, 382 U.S. at 339-40. *See also Wechsler v. Hunt Health Sys., Ltd.*, 285 F. Supp. 2d 343, 349 (S.D.N.Y. 2003) (explaining that *Beacon Theatres*’ “general prudential rule would work an

injustice antithetical to the very principles on which that case rests” if it were applied to require fraudulent conveyance jury trial to precede breach of contract bench trial, where parties to contracts signed jury waiver clauses and where fraudulent conveyance claim is predicated on factual determinations relating to breach of contract).

Finally, an additional reason that the Court does not need to order the infringement action first in time is that in instituting the interference proceeding – in which no right to a jury trial is available³ – Centocor waived its right to a jury trial on the corresponding issue of validity in the infringement action. Just as a creditor waives its right to a jury trial by voluntarily subjecting itself to the bankruptcy court’s equitable powers, *see, e.g., Langenkamp v. Culp*, 498 U.S. 42, 44-45 (1991), so too Centocor forfeited its right to a jury trial by electing to raise the issue of validity in an interference proceeding before the BPAI, rather than challenging the validity of Abbott’s patent in a district court proceeding.

III. CONCLUSION

For the foregoing reasons, Abbott respectfully submits that the decision of the BPAI on the issue of validity is final and should be accorded preclusive effect with respect to that same issue in the infringement case. If, however, the Court were to determine that the decision of the BPAI is not sufficiently final for purposes of the application of collateral estoppel, the Seventh Amendment would not prevent the Court from resolving issues of validity in the Section 146 action prior to or concurrently with holding a jury trial in the infringement action.

³ *See Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 604 (Fed. Cir. 1985) (“A defectively examined and therefore erroneously granted patent must yield to the reasonable Congressional purpose of facilitating the correction of governmental mistakes. This Congressional purpose is presumptively correct, and we find that it carries no insult to the Seventh Amendment and Article III.”).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that, on February 13, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ William F. Lee
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